

REMARKS

I. STATUS OF THE CLAIMS

Claims 1-26 are pending in this application.

Claims 23-25 are currently under examination.

Claims 23-25 stand rejected.

Claims 23, 24, and 25 are amended herein and claims 27-29 are newly added. No new matter is introduced.

II. AMENDMENTS TO THE CLAIMS

Claim 23 is amended herein to recite a process for preparing high density “calcium carbonate granulation,” to specify that the composition which is mixed in a high shear mixer comprises “calcium carbonate powder having a median particle diameter between about 0.1 and about 20 μm ,” to specify that the drying step employs a “fluidized bed oven,” and that the process results in a “calcium carbonate granulation having a tap density between about 0.9 g/cm^3 and about 2.0 g/cm^3 .” Support for these amendment is found throughout the specification and claims as originally filed, and particularly at ¶¶ 0011, 0015, 0023, 0037, and 0042.

Claim 24 is amended herein to specify that the calcium carbonate powder has a median particle diameter “between about 1 and about 15 μm .” Support for this amendment is found, for example, at ¶ 0011 of the application as originally filed.

Claim 25 is amended herein to specify that the calcium carbonate powder has a median particle diameter “between about 10 and about 12 μm .” Support for this amendment is found, for example, at ¶ 0023 of the application as originally filed.

Support for new claim 27 is found throughout the application as originally filed and in particular in original claim 25, Examples I-VI, and ¶ 0042.

Support for newly added claims 28 and 29, directed to granulated products and tablets, respectively, is found throughout the application, as filed, for example, at ¶¶ 0045 and 0046.

III. CLAIM REJECTIONS

Claims 23-25 stand rejected under 35 U.S.C. §103 as allegedly obvious over U.S. Patent No. 5,302,396 to Phadke et al. in view of “the Carrier fluid bed product document” cited by the Examiner. Claims 23-25 also stand rejected under 35 U.S.C. §103 as allegedly obvious over Gennaro (Remington: The Science and Practice of Pharmacy) in view of the Carrier fluid bed product document taken with Applicants’ admission that “many supplements include the use of calcium carbonate.” Applicants traverse these grounds of rejection on the basis that one skilled in the art would not have been motivated to combine the cited references to arrive at Applicants’ process for preparing high density granulation and, as such, the rejection is impermissibly based on hindsight. Nevertheless, in an effort to advance this case, Applicants have amended independent claim 23 herein to clearly distinguish the art of record. In view of the amendments to claim 23, the rejections are overcome, for at least the following reasons.

Independent claim 23 now recites the steps of “mixing a composition comprising calcium carbonate powder having a median particle diameter between about 0.1 and about 20 μm in a high shear mixer” and drying the composition in a “fluidized bed oven” to provide a “calcium carbonate granulation having a tap density between about 0.9 g/cm^3 and about 2.0 g/cm^3 .” These features of the claimed process, including the particle size of calcium carbonate and the density of the resulting granulation, are not remotely taught or suggested by the cited references, taken alone or in combination.

Moreover, the Phadke and Gennaro references actually teach away from the presently claimed invention. The stated goal of Phadke’s granulation process is to prepare “porous granules” [col. 2, lines 43-45]. Phadke states that the “bulk and tap density data indicate that for each sieve cut the porous granules had lower density than the control samples” (col. 4, lines 30-32). Phadke does not provide numerical data for the porous calcium carbonate granules discussed in column 3, lines 14-27, but does state that the bulk and tap densities showed that subject calcium carbonate granulation had “greater porosity” (i.e., was less dense) than control

calcium carbonate granules. Numerical data is provided for the mannitol granulations at column 4, lines 18-34. Notably, the highest tap density for Phadke's porous granules is 0.57 g/cc and the highest density for the control granules (i.e., granules without the effervescent mixture) was 0.59 g/cc. Thus, not only does Phadke fail to disclose a granulation process comprising the steps of high shear mixing the claimed calcium carbonate powder and fluidized bed drying, neither does it does disclose such a process to prepare granulation having a tap density of between about 0.9 g/cm³ and about 2.0 g/cm³. Because Phadke is making porous, low density granulation, it teaches away from the Applicants high density granulation process, as presently claimed.

Gennaro also teaches away from the presently claimed method of preparing high density granulation. Gennaro states that "fluidized bed granulation yields a less dense particle than conventional methods, and this can affect subsequent compression behavior" (p.1625). Applicants' claims relate to a "high density" calcium carbonate granulation and specify that the granulation has a tap density of between about 0.9 g/cm³ and about 2.0 g/cm³. Thus, one skilled in the art, seeking to prepare high density granulation, would have been led away from fluidized bed methods based on this disclosure of Gennaro.

In sum, claim 23 as presently amended fully distinguishes the art of record for at least the reasons that none of the references teach or suggest, either alone or in combination, that calcium carbonate powder "having a median particle diameter between about 0.1 and about 20 μ m" can be formed into a high density granulation having "a tap density of between about 0.9 g/cm³ and about 2.0 g/cm³" using a process comprising high shear mixing and fluidized bed drying. Applicants submit that the grounds of rejection are overcome.

With respect to claim 27 which now specifies that the type of dryer is a "horizontal fluidized bed oven," the Examiner has failed to establish that one skilled in the art would have been motivated to combine high shear mixing with horizontal fluidized bed drying in a granulation process for preparing high density calcium carbonate granulation. In essence, the Examiner contends with respect to both grounds of rejection that high shear mixing and horizontal fluidized bed drying were each, individually, known. Although the Gennaro and Phadke references mention high shear mixing, neither of these publications provide any motivation for combining such high shear mixing with the Carrier fluid bed product document

relating to equipment for carrying out horizontal fluidized bed drying.

According to the Examiner, one skilled in the art would have been motivated to combine high shear mixing with horizontal fluidized bed drying because the Examiner contends that Carrier fluid bed product document allegedly states that the Carrier equipment can “improve drying efficiency and uniformity of the product” (Office Action, ¶¶ 2 and 3). Regarding “drying efficiency,” the Carrier fluid bed product document states that “Carrier Vibrating Fluid Bed systems are specially designed to provide a continuous passage of air through the product bed - giving you a more efficient drying and cooling process at a minimum retention time because your material’s surface area contact is maximized” (p. 3). Applicants assume this is the language that the Examiner is referring to for the statement that the Carrier equipment can “improve drying efficiency.” Applicants fail to find a statement in the Carrier fluid bed product document relating to improved “uniformity of the product.” Rather, the Carrier fluid bed product document states that “[p]articles are mixed and turned to promote temperature uniformity and increase the speed of chemical reactions” (p. 3).

Nothing in the publications cited by the Examiner provided any evidence of a relationship between “drying efficiency” or “uniformity of product” and density. Thus, these statements would not motivate one skilled in the art, seeking to produce high density granulation, to utilize high shear mixing and horizontal fluidized bed drying in a granulation process. None of the publications, alone or in combination, provide a rationale for combining the steps of high shear mixing of a composition comprising calcium carbonate powder having a median particle size between about 0.1 and about 20 μm and drying in a horizontal fluidized bed oven, *in a granulation process*, to achieve a granulation having a density in the range of about 0.9 to about 2.0 g/cm^3 .

Regarding the rejection over Gennaro, the Examiner states that the “use of specific types of fluid bed dryers, such as horizontal, is not discussed.” Not only does Gennaro fail to disclose horizontal fluidized bed drying, Gennaro only discloses a specific type of fluidized bed dryer -- a vertical fluidized bed dryer. Gennaro states that “[w]hile tray drying was the most widely used method of drying tablet granulation in the past, fluidized bed drying is now equally popular” (p. 1623). The Examiner is evidently of the view that Gennaro is using the term “fluidized bed

drying” in a generic sense, arguing that because “it is not explicitly stated that any specific configuration is intended by the teaching” it therefore “can be reasoned that Gennaro’s teaching of using fluid bed dryers is not restricted to any specific configuration” (Office Action, p. 3). Applicants disagree.

As discussed in Applicants’ May 18, 2006 submission and the Rule 132 declaration of Dr. Gregory Urbanski submitted therewith, the only type of “fluidized bed” drying taught by Gennaro is a vertical fluidized bed dryer. There is simply no basis to support the Examiner’s contention that one skilled in art would consider Gennaro to refer to a “fluidized bed dryer” in a generic sense. Rather, Gennaro uses that phrase synonymously with “vertical fluidized bed drying.” The Examiner has not pointed to any teaching in Gennaro which would suggest otherwise.

The plain reading of Gennaro demonstrates that only vertical fluidized bed drying was contemplated. First, the sentence immediately following the reference to “fluid-bed dryers” on page 1623 of Gennaro states that “[i]n drying tablet granulation by fluidization, the material is suspended and agitated in a warm air stream while the granulation is maintained in motion” (pp. 1623-1624). This is consistent with vertical, not horizontal, fluidized bed drying. Further support that Gennaro only refers to vertical fluid bed dryers is provided by Gennaro’s statement that the materials is “suspended in a vertical column with a rising air stream” (p. 1625), as illustrated in Figure 12 of Gennaro. Thus, Applicants submit that this disclosure of Gennaro further clarifies that only vertical fluidized bed drying is contemplated. In addition, the discussion of “[d]rying tests comparing the fluidized bed and a tray dryer” on page 1624 of Gennaro explicitly references the “fluidized-bed granulation and drying” equipment of Figure 12, which unquestionably illustrates only vertical fluidized bed dryers. As explained in the Carrier fluid bed product document cited by the Examiner and in the Declaration of Dr. Urbanski, the horizontal fluidized bed achieves fluidization of the product bed through vibration of the conveyor deck, in contrast, to the suspension of particles in a warm air stream described by Gennaro. Applicants fail to find any additional discussion of fluidized-bed drying in Gennaro nor any basis to conclude that Gennaro is applicable to horizontal fluidized bed drying.

Further, the teachings of a prior art reference are to be construed from the viewpoint of one skilled in the art. Applicants submitted the declaration of Dr. Urbanski to assist the Examiner in understanding what Gennaro conveys to one skilled in the art. Dr. Urbanski declares that “[o]ne skilled in the art of granulation and drying would understand that Gennaro’s reference to ‘fluid-bed dryers’ relates solely to a particular type of fluid-bed dryer commonly known as a vertical fluidized bed.” The Examiner has not pointed to any evidence to suggest that one skilled in the art would read Gennaro as teaching otherwise. Applicants respectfully submit that the Examiner has given insufficient weight to Dr. Urbanski’s declaration and has failed to rebut the conclusion of Dr. Urbanski with factual evidence.

Because the entire discussion of fluidized bed drying in Gennaro relates only to vertical fluidized bed dryers, one skilled in the art would not have been motivated to employ horizontal fluidized bed drying in the granulation process described in Gennaro. For these reasons, reconsideration of the rejection over Gennaro is respectfully requested.

For at least the foregoing reasons, Applicants respectfully submit that independent claim 23, as presently amended, is patentable over the art of record. Because claim 23 fully distinguishes the art of record, its dependent claims are also patentable. Further, while the present amendments are intended to advance prosecution of this case, Applicants reserve the right to present claims of similar scope to originally filed claim 23 in a continuing application.

CONCLUSION

In view of the preceding amendments and remarks, Applicants submit that the amended claims fully distinguish over the art of record and believe that the application is in condition for allowance. If a telephone conference would facilitate prosecution of this application in any way, the Examiner is invited to contact the undersigned at the number provide below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13697.105006.

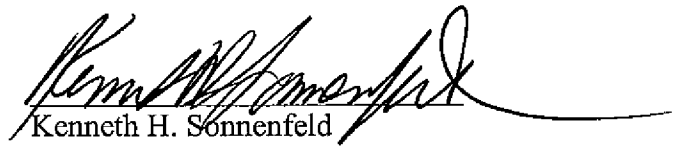
Furthermore, in the event that a further extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account No. 50-3732 and Order No. 13697.105006.

Respectfully submitted,

KING & SPALDING, L.L.P.

Dated: October 26, 2006

By:


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